

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Offic**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/426, 931 10/22/99 KNAPPE

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EXAMINER

CROSS, L

ART UNIT

PAPER NUMBER

1743

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DATE MAILED:

08/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Applicant No.	Applicant(s)
	09/426,931	KNAPPE, WOLFGANG-REINHOLD
	Examiner LaToya L. Cross	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 October 1999.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 29-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 29-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6.7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

In the specification at page 6, Applicants describe the R group as being "saturated and has one to three double bonds". It appears that Applicant intended "or" instead of "and" since the term "saturated" is given the meaning "having no double or triple bonds". Thus, the use of the phrase "saturated and has one to three double bonds" is contradictory.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 29-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29, 36-39, 41 and 47 recite "flat-shaped" which is indefinite. "Flat" is a term used to describe the texture of a surface and does not relate to shape.

In claim 31, it is unclear what is intended by "the structure and proportion in the mixture of the R groups corresponds to the structure and abundance of such groups in the natural fatty acids". Applicants must further clarify.

Claim 42 is worded in such a manner which is unclear. Applicants should clarify what is meant by "surface can be displaced freely relative to the strip surface covered by this part in the direction of curvature produced when the object is bent".

There is no antecedent basis for "the displaceable zones" in claim 43 and no antecedent basis for "the displaceable regions" in claim 44.

There is no antecedent basis for "the separation line" in claim 45.

There is no antecedent basis for "the analyte-sensitive region" or "the application spot" in claim 48.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 29, 30, 33, 35, 36, 39-42, 44, 46 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,194,224 to Good et al (hereinafter Good et al '224).

Applicants' invention is directed to a spreading material comprising a porous flat

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structure impregnated with a an N-acyl glycinate wetting agent. Also claimed is a process for manufacturing the material and a test strip comprising the spreading material.

Good et al '224 teach a diagnostic test strip for determining the presence of a specified analyte in a fluid sample. The test strip has a test membrane sandwiched between two layers. The test membrane has a sample receiving zone containing a buffer and a fatty acid sarcosinate. The sample receiving zone (21) is a pad made of non-woven fibrous material. The sample is absorbed by the pad, solubilizes the buffer and fatty acid sarcosinate and migrates to an adjacent reagent zone (22) containing reagent chemicals in fibrous matrix. The preferred sarcosinate is sodium myristoyl sarcosinate in a concentration of about 1.0 % by weight. Sodium myristoyl sarcosinate has a chemical formula embraced by that claimed by Applicants and is disclosed as being able to provide better flow characteristics to fluid specimens (col. 3, lines 34-38). Good et al '224 also disclose that the sample receiving zone is made by imbibing a solution containing a suitable buffer and fatty acid sarcosinate into a sheet to provide the appropriate concentration. See col. 4, lines 8-16 and col. 5, lines 8-27.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated within the meaning of 35 USC 102e in view of the teachings of Good et al '224.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 32, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al '224.

With respect to claim 32, Applicants recite the use of a mixture of N-acyl glycimates which is not disclosed by Good et al '224. However, it would have been obvious to one of ordinary skill in the art to use a mixture of glycimates although such is not specifically taught. MPEP 2144.06 states that combining two compounds useful for the same purpose would be obvious to the skilled artisan. One of ordinary skill in the art would have expected that using two or more glycimates would impart migrating/wetting properties in an at least additive amount, to the absorbing pad, absent evidence to the contrary.

With respect to claims 37 and 38, Good et al '224 teach that any desired size and shape of the sheet containing the sarcosinate may be used. One of ordinary skill in the art would have been able to determine what size absorbant pads would be suitable for any particular diagnostic strip.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,241,689 to Chard et al teaches a sample collection apparatus have a porous test strip which contains sarcosinate surface active/wetting agents to ensure good uptake of hydrophilic liquids such as saliva.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC *SLC*
August 22, 2001

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700